UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUCAMPO AG, SUCAMPO PHARMACEUTICALS, INC., SUCAMPO PHARMA, LLC, TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	**Civil Action No. 17-7451 (PGS) (LHG)** (Filed Electronically)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Patent Litigation") has been brought by Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., Sucampo Pharma, LLC (collectively, ("Sucampo"), Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda" and, together with Sucampo, "Plaintiffs") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") for infringement of United States Patent Nos. 6,414,016 ("the '016 Patent"), 8,071,613 ("the '613 Patent"), 7,795,312 ("the '312 Patent"), 8,748,481 ("the '481 Patent"), 6,982,283 ("the '283 Patent"), 8,026,393 ("the '393 Patent"), 8,097,653 ("the '653 Patent"), 8,338,639 ("the '639 Patent"), and 8,389,542 ("the '542 Patent") (collectively, the "Sucampo Patents"). Plaintiffs' commencement of the Patent Litigation was based on its receipt of notice from Teva that Teva

filed ANDA No. 209920 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sucampo Patents and seeking approval to market generic versions of 8 mcg and 24 mcg lubiprostone capsules.

Plaintiffs and Teva have now agreed to a good-faith final resolution regarding this Patent Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Teva during the Patent Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This Court shall retain jurisdiction over Plaintiffs and Teva to enforce the final settlement.[1] Plaintiffs and Teva also believe that this resolution gives them the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Patent Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Plaintiffs and Teva acknowledge there is significant risk to each of them associated with the continued prosecution of this Patent Litigation and have consented to judgment through a final resolution as reflected in the Consent Judgment set forth herein. The Court, upon the consent and request of Plaintiffs and Teva, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Order.

Plaintiffs and Teva now consent to this Consent Judgment and Order of Permanent Injunction and

IT IS, this 19 day of Sept, 2018,

HEREBY ORDERED, ADJUDGED AND DECREED that:

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[1] The parties agree to provide the Court, under seal, with a copy of their settlement upon request.

1. This Court has subject matter jurisdiction over this patent infringement action, and personal jurisdiction over Plaintiffs and Teva for purposes of this action. Venue is proper in this Court as to Plaintiffs and Teva as to this action.

2. In this Patent Litigation, which was filed on September 25, 2017, Plaintiffs have charged Teva with infringement of the Sucampo Patents in connection with Teva's submission of Abbreviated New Drug Application ("ANDA") No. 209920 directed to generic tablets containing 8 mcg and 24 mcg of lubiprostone per capsule ("Teva's ANDA No. 209920 Products") to the U.S. Food and Drug Administration ("FDA").

3. In response to Plaintiffs' charges of patent infringement, Teva has alleged certain defenses, including that the Sucampo Patents are invalid. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses.

4. Teva has not obtained a decision from the Court finding that it has rebutted the statutory presumption that the Sucampo Patents are valid and enforceable in the Patent Litigation.

5. Teva admits that the submission of ANDA No. 209920 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of Teva's ANDA No. 209920 Products within the United States before the expiration of the Sucampo Patents was a technical act of infringement of the Sucampo Patents under 35 U.S.C. § 271(e)(2)(A). This admission is further without prejudice to any claim, defense or counterclaim in any future action between Teva and Plaintiffs, or any successor-in-interest

to Sucampo, regarding the Sucampo Patents and/or a generic lubiprostone product other than Teva's ANDA No. 209920 Products.

6. Both parties have agreed that each of the defenses and counterclaims set forth in Teva's Answer, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Teva, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic capsule product containing 8 mcg and/or 24 mcg of lubiprostone per capsule that is the subject of ANDA No. 209920 until January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed.

8. Plaintiffs acknowledge that Teva is entitled to maintain their Paragraph IV certification to the Sucampo Patents pursuant to 21 C.F.R. § 314.94(a)(12)(v).

9. Plaintiffs and Teva each expressly waive any right to appeal or otherwise move for relief from this final Consent Judgment and Order of Permanent Injunction.

10. This Court retains jurisdiction over Plaintiffs and Teva for purposes of enforcing this final Consent Judgment and Order of Permanent Injunction.

11. This Consent Judgment and Order of Permanent Injunction is without prejudice to, and shall have no preclusive effect as to, any claim, defense or counterclaim in any future action between Teva or any successor-in-interest to Teva, and Plaintiffs, or any successor-in-interest to Plaintiffs, regarding the Sucampo Patents and/or a generic lubiprostone product other than Teva's ANDA No. 209920 Products.

12. The Clerk of the Court is directed to enter this final Consent Judgment and Order of Permanent Injunction forthwith, and thereafter close this matter.

IT IS HEREBY STIPULATED:

Dated: August 17, 2018

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SO ORDERED:

This 19 day of Sept, 2018.

Peter M Sheridan

THE HONORABLE PETER G. SHERIDAN
United States District Judge